

FLORA.0700



UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Copeland *et al.*

Atty Docket No.: FLORA.0700

Serial No.: 09/478,071

Group Art Unit: 1615

Filed: 01/03/2000

Examiner: N. Levy

TITLE: **HIGH UNSAPONIFIABLES AND METHODS OF USING THE SAME**

#### CERTIFICATE OF MAILING

*I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class mail in an envelope addressed to "Mail Stop: Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" on:*

Date: 11/03/2006

By: 

Printed Name: DOUGLAS W. GILMORE

#### AFFIDAVIT PURSUANT TO 37 C.F.R. §1.132

Assistant Commissioner of Patents  
Alexandria, VA 22313-1450

Dear Assistant Commissioner:

STATE OF ARIZONA            )  
  :  
COUNTY OF MARICOPA        )

I, David Ashley, being duly sworn, depose and say as follows:

I received a Bachelors of Science in Chemistry from Arizona State University in May of 1987. I have been employed by International Flora Technologies, Inc., (Technical Department) since 2003 where I serve as a chemist. Previously, I was employed at Safety-Kleen Systems, Inc., where I served as Compliance Manager from 2002-2003. I have also worked in various technical and managerial capacities at Onyx Environmental Services (Salesco Systems USA, Inc.), ADFlex Solutions Inc., and Revlon Consumer Products Corporation. I have over fourteen years of experience in analytical chemistry, environmental, health, and safety management. I am a Certified Hazardous Material Manager, and a member of the American Chemical Society.

I have undertaken an extensive review of United States Patent Application Serial No. 09/478,071. The invention referenced therein is directed to topical cosmetic formulations that include non-polar unsaponifiables (as defined in Official Methods of the American Oil Chemists Society, Ca 6a-40) in combination with polar hydrophilic salts, where the salts are produced as *in situ* products of hydrolysis of the original organic starting material. That is to say, United States Patent Application Serial No. 09/478,071 discloses a methodology for producing a cosmetic formulation containing non-polar unsaponifiable material in combination with polar hydrophilic salts in a unique and unconventional way. Specifically, the salt component disclosed in United States Patent Application Serial No. 09/478,071 is not pre-mixed, post-mixed or blended with unsaponifiable material (as may be expected in accordance with conventional approaches). Rather, the polar hydrophilic salts are synthetically produced within the formulation mixture itself by *in situ* hydrolyzation of a saponifiable component of originally supplied organic starting material (which original organic material simultaneously provides an unsaponifiable contribution to the resulting post-hydrolysis formulation).

The term "*in situ*" is a Latin phrase commonly used in the chemical industry to describe products of a reaction that are not removed or otherwise separated from original starting materials or the resulting post-reaction product mix. Merriam-Webster's Dictionary defines "*in situ*" as follows:

Pronunciation: (")in-'sI-(")tü, -'si-, -(")tyü *also* -'sE-, -(")chü

Function: *adverb or adjective*

Etymology: Latin, in position

: in the natural or original position or place <an *in situ* cancer confined to the breast duct>

see: <http://www.m-w.com/dictionary/in%20situ>

In accordance with the invention disclosed in United States Patent Application Serial No.09/478,071, the polar hydrophilic salts are formed from organic starting material during alkaline hydrolysis where the original starting material contains an unsaponifiable component. Neither the polar hydrophilic salts nor the unsaponifiable material are removed, segregated, or subjected to subsequent formulation blending or mixing.

This is not in keeping with conventional use of unsaponifiabiles. Conventional saponification methods employ steps for: addition and/or removal of salts from unsaponifiable material; discarding salts; and utilization of segregated unsaponifiable material. With conventional saponification, unsaponifiable components are removed from the products of saponification, as generally referenced in both Moy (U.S. Patent No. 5,928,659) and Koulbanis *et al.* (U.S. Patent No. 4,324,802).


Accordingly, the utilization of *in situ* products of hydrolysis of original organic starting material as disclosed in United States Patent Application Serial No. 09/478,071 has not previously been conventionally demonstrated or appreciated. Additionally, conventional cosmetic formulation methods have been directed toward blending and/or mixing unsaponifiable fractions of original organic materials with oils, as generally disclosed in Moy (U.S. Patent No. 5,928,659). United States Patent Application Serial No. 09/478,071 in no way discloses blending or mixing of unsaponifiable fractions of organic materials; rather United States Patent Application Serial No. 09/478,071 discloses a unique methodology for utilizing the combination of polar hydrophilic salts and non-polar unsaponifiabiles as *in situ* products of hydrolysis.

Accordingly, United States Patent Application Serial No. 09/478,071 provides benefits associated with (among other things) reduced costs of production that have not previously been appreciated or otherwise observed with conventional methods of saponification and/or conventional methods of cosmetic formulation. Other benefits associated with United States Patent Application Serial No. 09/478,071 include: increased substantivity as compared with material produced in accordance with conventional approaches, increased water resistance as compared with material produced in accordance with conventional approaches, demonstration of unique surfactant functionality as compared with material produced in accordance with conventional approaches, and the fact that formulations prepared in accordance with United States Patent Application Serial No. 09/478, 071 demonstrate substantially reduced (or even entirely absent) foaming action when combined with water as compared with formulations prepared in accordance with conventional approaches. Notably, the diminishment or absence of foaming action when combined with water is a unique and unexpected resultant property.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true. I further declare that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or

both, under Section 1001 of Title 18 of the United States Code and that such willful and false statements may jeopardize the validity of the subject patent application or any patent issued thereon.

I further declare that I have received no special compensation or consideration for making this affidavit, nor have I been in any way told, either directly or by implication or inference, by anyone that my employment by International Flora Technologies, Inc., or my professional advancement or other matters of personal or professional interest to me depend in any way on whether or not I make this affidavit or the content thereof. I further declare that I make this affidavit of my own free will and choice without any duress or influence of any kind, believing fully in the truth of the statements made by myself herein.

  
David Ashley

I, CAROL HYNES, a Notary Public in and for the County and State aforesaid, do hereby certify that David Ashley, whose name is subscribed to the foregoing instrument, appeared before me this day in person and acknowledge that he signed, sealed and delivered the said instrument as his free and voluntary act and deed for the uses and purposes therein set forth.

Given under my hand and Notary Seal this 12 day of October <sup>24</sup>~~Nov. 29~~ 2006.

My commission expires on 29 Nov. 2007

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